#### THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte MICHAEL S. KLICEK

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Appeal No. 98-0194 Application No.  $08/132,940^{1}$ 

ON BRIEF

Before MEISTER, FRANKFORT, and NASE, <u>Administrative Patent</u> <u>Judges</u>.

NASE, Administrative Patent Judge.

## DECISION ON APPEAL

This is an appeal from the refusal of the examiner to allow claims 1 through 18, as amended subsequent to the final rejection. These claims constitute all of the claims pending in this application.

<sup>&</sup>lt;sup>1</sup> Application for patent filed October 7, 1993.

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We AFFIRM-IN-PART and enter a new rejection pursuant to  $37 \ \text{CFR} \ \S \ 1.196(b)$  .

#### **BACKGROUND**

The appellant's invention relates to an automatic control for energy from an electrosurgical generator. An understanding of the invention can be derived from a reading of exemplary claims 1 and 18, which appear in the appendix to the appellant's brief.

The prior art references of record relied upon by the examiner as evidence of obviousness under 35 U.S.C. § 103 are:

4,582,057 Apr. 15, Auth et al. 1986 (Auth) Bowers et al. 4,727,874 Mar. 1, 1988 (Bowers) Rexroth et al. 4,739,759 Apr. 26, 1988 (Rexroth) Ensslin 5,167,658 Dec. 1, 1992

Claim 8 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the appellant regards as the invention.

Claims 1 through 8 stand rejected under 35 U.S.C. § 103 as being unpatentable over Bowers in view of Ensslin and Rexroth.

Claims 9 through 17 stand rejected under 35 U.S.C. § 103 as being unpatentable over Bowers in view of Ensslin, Rexroth and Auth. $^2$ 

Claim 18 stands rejected under 35 U.S.C. § 103 as being unpatentable over Bowers in view of Ensslin.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellant regarding the rejections, we make reference to the final rejection (Paper No. 9, mailed August 21, 1995) and the examiner's answer (Paper No. 18, mailed February 10, 1997) for the examiner's complete reasoning in support of the rejections, and to the appellant's

<sup>&</sup>lt;sup>2</sup> We note that while the examiner's answer (p. 5) does not contain a statement of this rejection, it does contain (p. 6) the same determination of obviousness based on Auth set forth in the final rejection (pp. 3-4). Accordingly, we will use the statement of this rejection as set forth in the final rejection.

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brief (Paper No. 17, filed October 2, 1996) for the appellant's arguments thereagainst.

## OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims, to the applied prior art references, and to the respective positions articulated by the appellant and the examiner. As a consequence of our review, we make the determinations which follow.

#### The indefiniteness issue

We do not sustain the rejection of claim 8 under 35 U.S.C.

§ 112, second paragraph.

The examiner determined (answer, p. 3) that claim 8 was "indefinite because exactly what constitutes the drive circuit being 'altered' [is] unclear." We do not agree.

The second paragraph of 35 U.S.C. § 112 requires claims to set out and circumscribe a particular area with a reasonable degree of precision and particularity. In re

Johnson, 558 F.2d 1008, 1015, 194 USPQ 187, 193 (CCPA 1977).

In making this determination, the definiteness of the language employed in the claims must be analyzed, not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art. Id.

The specification (page 9, lines 8-12) sets forth that the output from the electrosurgical generator 11 is terminated by altering the drive circuit 33 by using a relay 34 to disconnect and reconnect the power from the drive circuit 33. Therefore, it is abundantly clear to us that drive circuit 33, shown in Figures 1 and 2, constitutes the drive circuit being altered by feedback signal 28 to turn off the supply of high frequency electrosurgical energy to the active and return leads as recited in claim 8. Accordingly, we will not sustain the examiner's rejection.

### The obviousness issues

#### Claims 1, 13 and 18

We sustain the rejection of claims 1, 13 and 18 under  $35 \text{ U.S.C. } \S \ 103.^3$ 

Claim 1 recites an electrosurgical generator comprising, inter alia, an active electrode, an active lead, a return electrode, a return lead, a user control and an automatic control circuit. Claim 1 further recites that the automatic control circuit includes, inter alia, a voltage sensing circuit, a current sensing circuit, a multiplier, a clock, an integrator and a correlation circuit. The correlation circuit provides a feedback signal which alters the supply of energy to the active and return leads when the amount of energy calculated equals a reference signal sent from the user control.

<sup>&</sup>lt;sup>3</sup> For reasons set forth <u>infra</u>, we believe that claims 1, 13 and 18 are unpatentable over the combined teachings of Bowers and Ensslin. Accordingly, we consider the teachings of Rexroth and Auth to be cumulative with respect to these claims.

Claim 13 recites the same elements as set forth in claim

1 but in addition thereto recites that (1) the clock sets

units of time which are about a millisecond, and (2) the

feedback signal is used to terminate the electrosurgical

generator's supply of energy to the active and return leads by

altering a drive circuit thereof.

Claim 18 recites a method of automatically controlling an electrosurgical generator in response to the level of tissue impedance between active and return electrodes of the electrosurgical generator during tissue desiccation. The steps recited in claim 18 include, inter alia, (1) using an electrosurgical generator to supply energy to an active electrode and a return electrode; (2) setting the amount of energy desired for electrosurgery on a user control; (3) sensing the voltage level between the active and return leads; (4) sensing current flowing through the active or return lead; (5) calculating power flow with a multiplier receiving the sensed voltage level and current flow; (6) calculating with an integrator energy supplied through the leads per unit of time

utilizing the calculated power flow and a clock which establishes the units of time;

(7) providing a correlation circuit to generate a feedback signal when the amount of energy calculated equals the user control setting (from step (2)); and (8) altering the supply of energy to the active and return leads in accord with the feedback signal.

Bowers discloses an electrosurgical generator with a high-frequency pulse width modulated feedback power control.

As shown in Figure 1, the electrosurgical generator 10 includes

a control panel 12 having the typical switches and other control devices for controlling the mode of operation of the generator 10 and the amount of power to be delivered in each mode and may include means for adjusting the blend or relative amounts of cutting and hemostasis which occurs during the cutting with hemostasis mode of operation. A power output control signal 18 is supplied from the control panel 12 to control and generally limit the DC power output 20 from the supply 16 according

to the amount of power desired. A high-frequency surgical signal is applied to conductor 32, which is connected to the active electrode used by the surgeon. Conductor 34 is the reference potential conductor for the high-frequency surgical signal and it is connected to the patient plate or inactive electrode upon which the patient is positioned. bipolar electrosurgical instrument is used, both conductors 32 and 34 are connected to the instrument. Bowers' electrosurgical generator also includes (1) a current sensor 36 connected in series in the conductor 32 for the purpose of deriving an instantaneous current sense signal 38 which is related to the instantaneous magnitude of current flowing in the conductor 32, and (2) a voltage sensor 40 electrically connected between the conductors 32 and 34 for the purpose of deriving an instantaneous voltage sense signal 42 representative of the instantaneous voltage existing between the conductors 32 and 34. Accordingly, both the instantaneous output current and voltage of the high-frequency surgical signal are sensed at a point in the generator 10 where the surgical signal is delivered. The current signal 38, 48, 68 and the voltage signal 42, 50, 70 are thereafter supplied to a conventional analog multiplier 72 to generate a delivered power signal 74 representative of the delivered power. A selected power signal 66 is provided by adjustment of a conventional potentiometer (not shown) at the control panel 12 and represents the desired level of power. The selected power signal 66 is supplied to a scaling circuit 60 which generates signal 76 representative of the desired output power level. The desired output power signal 76 and the delivered power signal 74 are compared at a differential amplifier 78 and an error signal 80 is generated. This error signal 80 represents the difference in magnitude between the delivered power and the desired power. A pulse width modulation circuit 82 receives the error signal 80 and utilizes the error signal to create a pulse width control signal 84. An amplifier drive circuit 86 receives the pulse width control signal 84 and creates a drive signal 90 which controls the operation of the amplifier 22 of the generator 10. Each driving pulse establishes the width and hence energy content of each pulse of the pulse width modulated signal 24. The width of each pulse of the pulse width modulated signal regulates the output power of each cycle of the surgical signal. Thus, this power is ultimately controlled by the pulse width control signal 84.

Ensslin discloses a method and apparatus for determining the amount of energy dispensed during an electrosurgical procedure into a patient. Ensslin teaches that as a consequence of common electrosurgical procedures, significant amounts of energy are dispensed to a patient's body and that for reasons of patient safety, and consistent with conservative surgical procedures generally, it is desirable for a surgical team to be able to estimate with reasonable accuracy the amount of electrical energy

dispensed into a patient over discrete intervals of time involved in the surgical procedures. Ensslin states (column 1, lines 39-45) that

[i]t is particularly important for the surgical team to monitor the total energy dispensed into the patient's body during the entire procedure from start to finish. Unfortunately, available electrosurgical devices provide no reliable basis from which accurate determinations of energy dispensed into a patient can be derived.

Figure 3 of Ensslin illustrates a typical system utilized for electrosurgical procedures but modified by the inclusion of components useful for the practice of his invention. electrosurgical generator 30 has terminals 31, 32 to which are connected a dispersive patient plate electrode 35 and an electrosurgical instrument electrode 36, respectively. Conductors 33 and 34 extend from terminals 31 and 32, respectively, to connect the dispersive patient plate electrode 35 and the electrosurgical instrument electrode 36 as shown. Current flowing through the circuit is detected at conductor 33 by means of a current transformer device 45, the leads 47, 49 of which are connected to the terminals 51, 53, respectively, of an analog to digital converter device 55. An output 57 from the converter 55 is fed to a central processing unit 60 (referred to hereinafter as a "CPU"). The CPU 60 is connected by an input cable 63 and an output cable 65 to the electrosurgical generator 30. The CPU 60 is programmed to recognize the power setting (percent maximum power) of the generator 30, and to determine the actual load impedance of the circuit from the detected current value by reference to the mathematical relationship between current and impedance

characteristic of the generator 30 at that power setting. A family of such relationships, as illustrated by Figure 2, may be stored in memory. The CPU is further programmed to calculate the power delivered to the surgical target from the detected current value and the derived impedance value, such calculations being well-known in the art. Any or all of the electrical quantities detected, derived, or calculated may be stored in memory or forwarded to one or more display devices 70 or a printer 75. Ensslin then teaches (column 4, lines 12-21) that

[i]t is ordinarily desirable for the CPU to perform the calculations in real time. It is then feasible for the CPU to control the electrosurgical generator in response to detected current, calculated power, total energy dispensed, or any combination of these parameters. For example, it may sometimes be desirable for the generator 30 to be automatically shut down in response to signals from the CPU indicating that a predetermined amount of energy has been dispensed to the target 40 either over a prescribed increment of time or since the commencement of a procedure.

Ensslin also discloses (column 2, lines 40-54) that the computer integrates power over time and drives auxiliary devices which can terminate power after a predetermined amount of total energy has been dispensed to the patient. Thus,

Ensslin inherently discloses that his computer includes a clock and an integrator.

After the scope and content of the prior art are determined, the differences between the prior art and the claims at issue are to be ascertained. Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966).

Based on our analysis and review of Bowers and claim 1, it is our opinion that the only differences are the limitations that

(1) the user control sets the level of energy desired by the user, (2) the automatic control circuit includes a clock and an integrator to calculate the amount of energy supplied from the calculated power flow, and (3) the correlation circuit provides a feedback signal which alters the supply of energy to the active and return leads when the amount of energy calculated equals the reference signal sent from the user control.

Based on our analysis and review of Bowers and claim 13, it is our opinion that the only differences are the limitations

that (1) the user control sets the level of energy desired by the user, (2) the automatic control circuit includes a clock which sets units of time of about a millisecond and an integrator to calculate the amount of energy supplied from the calculated power flow, and (3) the correlation circuit is a comparator which is used to terminate the electrosurgical generator's supply of energy to the active and return leads by altering a drive circuit thereof when the amount of energy calculated equals the reference signal sent from the user control.

Based on our analysis and review of Bowers and claim 18, it is our opinion that the only differences are the limitations that (1) the user control sets the level of energy desired by the user, (2) a clock and an integrator calculate the amount of energy supplied from the calculated power flow, and (3) the correlation circuit provides a feedback signal which alters the supply of energy to the active and return leads when the amount of energy calculated equals the reference signal sent from the user control.

In applying the test for obviousness, we reach the conclusion that it would have been obvious to one of ordinary skill in the art at the time of the appellant's invention to provide Bowers' electrosurgical generator with an energy measuring and control means as suggested and taught by Ensslin so that Bowers' electrosurgical generator would be automatically shut down in response to signals from a CPU indicating that a predetermined amount of energy has been dispensed either over a prescribed increment of time or since the commencement of a procedure. In that regard, it is our opinion that based upon the combined teachings of Bowers and Ensslin that one skilled in the art would have (1) provided Bowers' electrosurgical generator with a clock and an integrator to calculate energy per unit of time based upon Bowers' power signal 74, (2) compared the calculated energy per

<sup>&</sup>lt;sup>4</sup> The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art. See In re Young, 927 F.2d 588, 591, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991) and In re Keller, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). Moreover, in evaluating such references it is proper to take into account not only the specific teachings of the references but also the inferences which one skilled in the art would reasonably be expected to draw therefrom. In re Preda, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968).

unit of time to a user energy setting set on Bowers' control panel 12, and (3) automatically shut down Bowers' electrosurgical generator when that amount of energy dispensed equals the user energy setting. In addition, with respect to claim 13, we believe it would also have been obvious to one of ordinary skill in the art at the time of the appellant's invention to set the units of time of the clock to be about a millisecond in view of Ensslin's teaching of performing the integration continuously in real time.

The appellant's arguments are unpersuasive for the following reasons. First, the appellant argues (brief, pp. 12-13) that Bowers contains "no instruction therein to control energy" and that Ensslin "does not have a voltage measuring circuit." As to the appellant's argued deficiencies of each reference on an individual basis, we note that nonobviousness cannot be established by attacking the references individually when the rejection is predicated upon a combination of prior art disclosures. See In re Merck & Co. Inc., 800 F.2d 1091, 1097, 231 USPQ 375, 380 (Fed. Cir. 1986). Second, the appellant argues (brief, pp. 14, 21 and 22) that there is no

motivation found in the cited references to make the combination. We do not agree. It is our opinion that Ensslin's teaching that it is particularly important for the surgical team to monitor the total energy dispensed into the patient's body during the entire procedure from start to finish provides the motivation to the person of ordinary skill in this art to provide electrosurgical devices such as Bowers with a system from which accurate determinations of energy dispensed into a patient can be derived so that the electrosurgical devices can be automatically shut down when the amount of energy dispensed equals a predetermined energy setting. we agree with the appellant's technical background (brief, pp. 10-11) that power and energy are different and that one skilled in the art would not substitute Ensslin's energy regulation for Bowers' power regulation. However, for the reasons set forth above, we believe it would have been obvious to add Ensslin's energy regulation to Bowers' power regulation to gain the self evident advantages thereof. Lastly, the appellant argues (brief, p. 20) that applied prior art does not suggest the added elements of claim 13. We do not agree. As pointed above, it is our determination that the only element added by

claim 13 not specifically suggested or taught by the combined teachings of Bowers and Ensslin is the recitation that the clock sets the units of time of about a millisecond. However, while Ensslin is silent as to the units of time utilized, we observe that an artisan must be presumed to know something about the art apart from what the references disclose (<a href="mailto:see In re Jacoby">see In re Jacoby</a>, 309 F.2d 513, 516, 135 USPQ 317, 319 (CCPA 1962)) and the conclusion of obviousness may be made from "common knowledge and common sense" of the person of ordinary skill in the art (<a href="mailto:see In re Bozek">see In re Bozek</a>, 416 F.2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969)). Based upon the "common knowledge and common sense" of the artisan, it is our opinion that it would have been obvious to set the units of time of the clock to be about a millisecond especially in view of Ensslin's teaching of performing the integration continuously in real time.

## Claims 9 through 12 and 14 through 17

We do not sustain the rejection of claims 9 through 12 and 14 through 17 under 35 U.S.C. § 103.

Dependent claims 9 and 14 each recite the limitation that

the user control has two added adjustors one for setting a number of packets of energy and another for a preset level of energy delivered per packet.

The above-noted limitations are not taught or suggested by Bowers, Ensslin or Rexroth. Therefore, the examiner applied Auth. Specifically, the examiner determined (answer, p. 6) that

Auth et al teaches the desirability of controlling the number of energy pulses administered to a patient. It would have been obvious to the artisan of ordinary skill to control the number of pulses delivered, since this is an [sic, a] recognized way of controlling the energy delivered to tissue, as taught by Auth et al.

The appellant argues (brief, pp. 18-19) that the specifically claimed circuit "would not have been an obvious combination." We agree. In fact, even if the references were combined as set forth by the examiner, the resulting device would not have the user control as set forth in claims 9 and 14. Specifically, the two added adjustors (i.e., one for setting a number of packets of energy and the other for a preset level of energy delivered per packet) recited in claims 9 and 14 are not suggested by the applied prior art. Since all the limitations of dependent claims 9 and 14 are not suggested

by the applied prior art, we cannot sustain the examiner's rejection of appealed claims 9 and 14, or claims 10 through 12 and 15 through 17 which depend therefrom, under 35 U.S.C. § 103.

## Claims 2 through 8

The appellant has grouped claims 1 through 8 as standing or falling together. Thereby, in accordance with 37 CFR § 1.192(c)(7), dependent claims 2 through 8 fall with independent claim 1. Thus, it follows that the examiner's rejection of claims 2 through 8 under 35 U.S.C. § 103 is also sustained.

#### New ground of rejection

Under the provisions of 37 CFR § 1.196(b), we enter the following new ground of rejection.

Claim 8 is rejected under 35 U.S.C. § 112, first and second paragraphs, for the reasons set forth below.

<sup>&</sup>lt;sup>5</sup> See pages 8-9 of the appellant's brief.

Original claim 8 was rejected under 35 U.S.C. § 112, second paragraph, in the second Office action (Paper No. 5, mailed January 11, 1995) for the same reason which we have reversed above. In an attempt to overcome this rejection, the appellant amended claim 8 (Paper No. 7, filed April 27, 1995) to add at the end thereof the phrase "in accord with the feedback quantity to narrow the difference between the energy calculations and the setting of the user control." We find this "added phrase" to violate the first and second paragraphs of 35 U.S.C. § 112 for the following reasons.

The "added phrase" is indefinite for failing to particularly point out and distinctly claim the subject matter which the appellant regards as the invention. In this regard, we note that ther is no proper antecedent basis for "the feedback quantity." Thus, it would be unclear to the artisan which element the limitation is intended to refer. We note that independent claim 1 recites "a feedback signal" not "a

<sup>&</sup>lt;sup>6</sup> The deletion of the "added phrase" from claim 8 would overcome this new ground of rejection.

feedback quantity." Additionally, since the feedback signal 28 is generated only when

the energy calculations equal the setting of the user control, the claimed difference between the energy calculations and the setting of the user control being narrowed appears to be misdescriptive.

The "added phrase" lacks the required written desciption, as the specification, as originally filed, does not provide support for the invention as is now claimed.

## CONCLUSION

To summarize, the decision of the examiner to reject claim 8 under 35 U.S.C. § 112, second paragraph, is reversed; the decision of the examiner to reject claims 1 through 8, 13 and 18 under 35 U.S.C. § 103 is affirmed; and the decision of the examiner to reject claims 9 through 12 and 14 through 17 under 35 U.S.C. § 103 is reversed.

In addition to affirming the examiner's rejection of one or more claims, this decision contains a new ground of

rejection pursuant to 37 CFR § 1.196(b)(amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53131, 53197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. Office 63, 122 (Oct. 21, 1997)).

37 CFR § 1.196(b) provides, "A new ground of rejection shall not be considered final for purposes of judicial review."

Regarding any affirmed rejection, 37 CFR § 1.197(b) provides:

- (b) Appellant may file a single request for rehearing within two months from the date of the original decision . . .
- 37 CFR § 1.196(b) also provides that the appellant, <u>WITHIN</u>

  TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (37 CFR § 1.197(c)) as to the rejected claims:
  - (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
  - (2) Request that the application be reheard under  $\S 1.197(b)$  by the Board of Patent Appeals and Interferences upon the same record. . . .

Should the appellant elect to prosecute further before the Primary Examiner pursuant to 37 CFR § 1.196(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If the appellant elects prosecution before the examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR  $\S 1.136(a)$ .

AFFIRMED-IN-PART; 37 CFR § 1.196(b)

JAMES M. MEISTER Administrative Patent	Judge	)		
		)		
CHARLES E. FRANKFORT		)	BOARD OF	
Administrative Patent	Judge	)	AND TNTERFERENCES	
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JEFFREY V. NASE Administrative Patent	Judge	)		

PETER C. RICHARDSON
PFIZER INC.
235 E. 42ND ST.
NEW YORK, NY 10017-5755

# APPEAL NO. 98-0194 - JUDGE NASE APPLICATION NO. 08/132,940

APJ NASE

APJ MEISTER

APJ FRANKFORT

DECISION: AFFIRMED-IN-PART

37 CFR § 1.196(b)

Prepared By: Delores A. Lowe

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1st Rev 23 Mar 98

FINAL TYPED: